



Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title: Amendment 9 to the Global Harmonization Working Party Terms of Reference and House Rules

Authoring Group: GHWP SECRETARIAT

Date: 9th September 2024

1. Purpose

This document proposes to make amendment to the Global Harmonization Working Party (GHWP) Terms of Reference and House Rules (hereafter as “GHWP TOR and House Rules”) as detailed in section 3 below under “Proposed Amendments to the GHWP TOR and House Rules”.

2. Background

2.1. The current GHWP TOR is specified under the Final Document GHWP/SECRETARIAT/F001:2021 resolved in the 25th GHWP Meeting and announced on 1st Dec 2021, and the current GHWP House Rules is specified under the Final Document GHWP/SECRETARIAT/F001:2023 resolved in 26th GHWP Meeting and announced on 16th Feb 2023.

2.2. This amendments of TOR and House Rules mainly incorporate the provisions to formalize the electronic voting by eligible voters as an option to the voting during GHWP Meetings via physical presence by eligible voters.

2.3. The amendments will follow the below general principles: -

2.3.1. The eligibility of voting rights, therefore one vote from regulatory authority and one vote from industry in each member country/region, remains unchanged.

2.3.2. GHWP & GHWPTC Terms of Reference can override the GHWP House Rules when there is any discrepancy.

3. Proposed Amendments to the GHWP TOR and House Rules

3.1. The following new provision(s) as shown in bold and underlines, or edits as shown in bold and with stroke lines, are the proposed amendments to the corresponding clauses in the GHWP TOR and House Rules: -

A. GHWP TOR Clause 1.5 on Leadership:

One GHWP Chair and two GHWP Vice-chairs shall be elected from Primary GHWP Representatives at the GHWP Annual Meeting through voting by all presented Primary GHWP Representatives or **by electronic voting** for a term of office until the next election. The GHWP Chair and one GHWP Vice-chair shall come from Regulatory Authorities while one GHWP Vice-chair shall come from the Industry. The GHWP Chair and Vice-chairs will normally rotate among members.

B. GHWP TOR Clause 1.6 on Official Observers:

The GHWP leadership may designate Official Observers on the basis of expected contribution and value. Official Observers must be approved by the unanimous consent of the voting members present in GHWP annual

meetings **or by electronic voting**. Official Observers do not participate in the decision making process.

C. GHWP TOR Clause 1.7 on Decisions and Resolutions:

The Working Party shall operate on a consensus basis. Decisions and resolutions on key issues and controversial matters should be made only after thorough discussions before voting at GHWP Meetings **or by electronic voting**. Though members should adopt as far as possible the decisions and resolutions so passed, such decisions and resolutions are not binding on members such that they may elect alternatives and decide their own implementation plans taking account of their local situations.

D. GHWP TOR Clause 2.3 on GHWPTC Leadership:

One GHWPTC Chair and two GHWPTC Co-chairs shall be elected by the GHWP Primary Representatives among the GHWPTC Representatives at the GHWPTC Meeting that is held in conjunction with the GHWP Annual Meeting **or by electronic voting**. The GHWPTC Chair and one GHWPTC Co-chair shall come from the Regulatory Authorities while one GHWPTC Co-chair shall come from the Industry. In the absence of the GHWPTC Chair at a given GHWPTC Meeting, the GHWPTC Co-chair from the Regulatory Authority shall assume the duties of the GHWPTC Chair. In the absence of both the GHWPTC Chair and Co-chair from the Regulatory Authority, the GHWPTC Co-chair from the Industry shall assume the duties of the GHWPTC Chair.

E. GHWP TOR Clause 3.2 on Resolutions, Endorsements & Decisions:

- (A) GHWP and GHWPTC Representatives may initiate resolutions and recommendations for discussions and voting at the GHWP Meetings and GHWPTC Meetings respectively **or by electronic voting**. Requests shall be made to the GHWP Secretariat and copied to the GHWP Chair and GHWPTC Chair at least one week before the relevant Meeting. Any proposed amendments to the resolutions shall be made to the GHWP Secretariat and copied to the GHWP Chair and GHWPTC Chair at least one day before the relevant meeting.
- (B) A simple majority is needed for passing any resolutions and recommendations at the GHWP Meetings and GHWPTC Meetings respectively **or by electronic voting**.
- (C) GHWPTC Representatives may initiate resolutions of GHWPTC technical documents and white papers for discussions and endorsements through electronic means and/or at GHWPTC Meetings by GHWPTC Representatives.
- (D) A simple majority is needed for any endorsements of GHWPTC technical documents and white papers through electronic means by GHWPTC Representatives.

F. GHWP TOR Clause 4.1 on Voting:

Each Primary GHWP Representative shall have one vote at the GHWP Meeting **or during electronic voting**. Each Primary GHWPTC

Representative shall have one vote at GHWPTC Meeting **or during electronic voting in GHWPTC.**

- G. GHWP TOR Clause 4.5 on Change of Office Bearers and Representatives:
When there are changes to office bearers, the Primary GHWP Representative of the corresponding country or region shall nominate replacements to fill any vacancies arise. If the Primary GHWP Representative of the country or region fails to make nominations for such replacements for any reason, the GHWP Chair may appoint acting replacements until new office bearers are elected to fill the relevant vacancies in the next GHWP Meeting **or by electronic voting.**
- H. GHWP TOR Clause 4.6 on Representation in the absence of the Representatives:
Secondary GHWP and GHWPTC Representatives could take up all the roles and responsibilities as well as voting rights of the corresponding Primary GHWP and GHWPTC Representatives in their absence **to Meetings or failed to cast their votes electronically by the deadline.** In case that both the Primary and Secondary GHWPTC Representatives are absent, the corresponding Primary GHWP Representative could take up all the roles and responsibilities as well as voting rights at the GHWPTC Meetings. **For electronic voting, in case both the Primary and Secondary GHWPTC Representatives failed to cast their votes by the deadline, the corresponding Primary GHWP Representative could take up all the roles and responsibilities as well as voting rights.** Similarly, Primary GHWPTC Representatives could take up all the roles and responsibilities as well as voting rights ~~at GHWP Meetings~~ if the corresponding Primary and Secondary GHWP Representatives are both absent at GHWP Meetings **or failed to cast their votes by the deadline.** However, representatives from the Regulatory Authority shall not represent representatives from the Industry. Similarly, representatives from the Industry shall not represent representatives from the Regulatory Authority.
- I. GHWP House Rules Clause 8 on Applications for Joining GHWP:
- (A) The Regulatory Authority of any country or region interested in joining GHWP shall send the application form to the Secretariat.
 - (B) The Secretariat shall inform the GHWP Chair upon the confirmation of the application.
 - (C) The applicants will be invited to attend the next GHWP Meeting where voting on their applications will take place **or voting on their applications will be taken place electronically.**
- J. GHWP House Rules Clause 11 on Hosting GHWP and GHWPTC Meetings:
- (A) Members intend to host any GHWP and/or GHWPTC Meetings shall plan ahead before making applications. They shall inform the GHWP Chair, GHWPTC Chair and Secretariat of their intention as early as possible. If there is more than one applicant, the decision shall be made in the GHWP Meeting **or by electronic voting** through voting by Primary GHWP Representatives and the one

with the highest number of votes will be selected. The chair of the meeting can cast an extra vote when there is more than one applicant having the highest number of votes. GHWP Meetings are normally held on yearly basis while the GHWPTC Meetings are held on need basis.

- K. GHWP House Rules Clause 16 on Proposing Resolutions in GHWP Meetings:
- (A) Resolutions shall be initiated for disputable issues after discussions so as to seek majority views from all GHWP members. Resolutions are only GHWP policies and/or recommendations that shall not be binding on members.
 - (B) Chairs of committees, working groups, special task groups, the Secretariat, GHWP Representatives and GHWPTC Representatives could propose resolutions that shall reach the Secretariat at least one week before the GHWP Meeting. The Secretariat shall post the proposed resolutions and related documents, if any, on the website and add them to the meeting agendas.
 - (C) All proposed resolutions shall be discussed and voted in the GHWP Meeting **or by electronic voting**. A simple majority is needed to pass the resolution.

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